REMARKS

Applicants have studied the Office Action mailed May 19, 2006. It is respectfully submitted that the application, as amended, is in condition for allowance. Reconsideration and allowance of the pending claims in view of the above amendments and following remarks is respectfully requested.

Status of parent priority applications in first line of specification:

The Examiner stated that Applicant is required to update status of all parent priority applications in the first line of specification.

Applicants respectfully assert that, because the parent priority applications were indicated in an Application Data Sheet, they do not also need to be referenced in the first line of specification. Furthermore, the Filing Receipt mailed May 12, 2005 indicates the current status (i.e., issued patent numbers) of the parent priority applications.

Objection to the specification:

The Examiner objected to the disclosure because it contains an embedded hyperlink (page 12, lines 23 and 27).

The hyperlinks at page 12, lines 23 and 27, which were the only hyperlinks in the specification, are hereby deleted, as indicated above by the amendments to the specification.

Rejection of claims 3 and 27-39 under 35 USC §102(e) as being anticipated by Yue et al.:

The Examiner stated that claims 3 and 27-39 are rejected under 35 USC §102(e) as being anticipated by Yue et al. (WO 01/96547).

In making this rejection, the Examiner states that Yue et al. teach an isolated antibody that selectively binds to a polypeptide called PKIN, which is 100% sequence identical to claimed SEQ ID NO:2 over amino acids 1-252 and 98% overall (amino acids 1-257). The Examiner further states that Yue et al. teach both polyclonal and monoclonal antibodies that bind the PKIN protein, Yue et al. teach administering the antibody with a detectable substance, Yue et al. teach antibodies used in compositions with a pharmaceutically acceptable carrier, and Yue et al. teach fragments of antibodies such as Fab, and $F(ab')_2$ and Fv. The Examiner also states that the

antibody or antibody fragments of Yue et al. bind to a polypeptide that contains 497 amino acids of which the first 252 amino acids are identical to claimed SEQ ID NO:2, and the claimed sequence contains only five amino acids at the C-terminus that are not included in the sequence of Yue et al. Therefore, it is the Examiner's contention that any polyclonal or monoclonal antibodies raised using SEQ ID NO:2 would cross-react with PKIN protein of Yue et al.

In response, Applicants respectfully assert that Yue et al. does not anticipate claims 3 and 27-39 and that the rejection of these claims under 35 USC §102(e) should be reconsidered and withdrawn.

The Examiner asserts, in effect, that the antibody taught by Yue et al. will inherently cross-react with the same polypeptides (i.e., polypeptides comprising or consisting of SEQ ID NO:2) as the instantly claimed antibodies, thereby anticipating the instant claims. However, inherency may only be relied upon where the consequences of following the reference disclosure always necessarily results in the claimed invention. If there is not a reasonable certainty that the claimed subject matter will necessarily result, the rejection is not proper.

Specifically, in order for the antibody of Yue et al. to inherently anticipate the instant claims, the antibody of Yue et al. must necessarily selectively bind to the polypeptides recited in the instant claims (i.e., polypeptides comprising or consisting of SEQ ID NO:2). It is not sufficient that the antibody of Yue et al. may possibly or probably bind to the polypeptides recited in the instant claims.

However, this "possibly or probably" standard appears to be the standard that the Patent Office is relying on for the rejection of claims 3 and 27-39 under 35 USC §102(e). The Examiner has cited a reference that teaches an antibody that may possibly or probably selectively bind to polypeptides of SEQ ID NO:2 because the reference antibodies bind to a protein that has an amino acid sequence that is partially identical to SEQ ID NO:2, without demonstrating that the reference antibodies must necessarily selectively bind to polypeptides of SEQ ID NO:2.

It is Applicant's position that the antibody of Yue et al. does not necessarily selectively bind to polypeptides of SEQ ID NO:2 because significantly different epitopes must necessarily exist in the polypeptide of SEQ ID NO:2 compared with the PKIN protein of Yue et al. because of the extensive differences that exist in their amino acid sequences. For example, the amino acid sequence of instant SEQ ID NO:2 differs from the PKIN protein of Yue et al. by not only the five amino acids at the C-terminus of instant SEQ ID NO:2 that are not included in the sequence of

Yue et al., but also the additional 241 amino acids that are present in the PKIN protein of Yue et al. (which is 497 amino acids in length) that are not present in instant SEQ ID NO:2 (which is 257 amino acids in length).

Thus, any epitopes in instant SEQ ID NO:2 that span any of the extra five amino acids amino acids at the C-terminus of instant SEQ ID NO:2 that are not included in the sequence of Yue et al. would not be present in the PKIN protein of Yue et al. Similarly, any epitopes that span any portion of the additional 241 amino acids that are present in the PKIN protein of Yue et al. compared with instant SEQ ID NO:2 would not be present in instant SEQ ID NO:2. Because of the different epitopes present in each of instant SEQ ID NO:2 and the PKIN protein of Yue et al., antibodies raised using one of these proteins will not necessarily cross-react with the other protein. Accordingly, not all antibodies raised using instant SEQ ID NO:2 would cross-react with the PKIN protein of Yue et al., and not all antibodies raised using the PKIN protein of Yue et al. would cross-react with instant SEQ ID NO:2.

Furthermore, because the PKIN protein of Yue et al. has 241 additional amino acids compared to instant SEQ ID NO:2, it is quite likely that any antibodies to the PKIN protein disclosed by Yue et al. bind to epitopes spanning at least a portion of this 241 amino acid region of the PKIN protein. These epitopes are not present in instant SEQ ID NO:2 and thus any such antibodies disclosed in Yue et al. would not bind to instant SEQ ID NO:2. Therefore, these antibodies in Yue et al. would not be encompassed by the instant claims. Because there is a reasonable degree of likelihood that the antibodies disclosed in Yue et al. do not anticipate the instant claims, the rejection under 35 USC §102 is improper.

Therefore, due to the significant differences in the protein structures of the PKIN protein of Yue et al. and instant SEQ ID NO:2, the antibody taught by Yue et al. does not necessarily cross-react and selectively bind to the same proteins (i.e., proteins comprising or consisting of SEQ ID NO:2) as the antibodies of claims 3 and 27-39.

Accordingly, Applicants respectfully request that the rejection of claims 3 and 27-39 under 35 USC §102(e) be reconsidered and withdrawn.

Rejection of claims 3 and 27-39 under 35 USC §102(e) as being anticipated by Yu et al.:

The Examiner stated that claims 3 and 27-39 are rejected under 35 USC §102(e) as being anticipated by Yu et al. (U.S. Patent Application Publication 2002/0123622).

In making this rejection, the Examiner states that Yu et al. teach an isolated antibody that selectively binds to a polypeptide called NHP, which is 100% sequence identical to claimed SEQ ID NO:2 over amino acids 1-252 and 98% overall (amino acids 1-257). The Examiner further states that Yu et al. teach both polyclonal and monoclonal antibodies that bind the NHP protein, Yu et al. teach fragments of antibodies such as Fab, and $F(ab')_2$ and Fv, Yu et al. teach that the antibodies may be administered as part of patient treatment methods, and Yu et al. further teach antibodies with a detectable label. The Examiner also states that the antibody or antibody fragments of Yu et al. bind to a polypeptide that contains 1958 amino acids of which the first 252 amino acids are identical to claimed SEQ ID NO:2, and the claimed sequence contains only five amino acids at the C-terminus that are not included in the sequence of Yu et al. Therefore, it is the Examiner's contention that any polyclonal or monoclonal antibodies raised using SEQ ID NO:2 would cross-react with the NHP protein of Yu et al.

In response, Applicants respectfully assert that Yu et al. does not anticipate claims 3 and 27-39 and that the rejection of these claims under 35 USC §102(e) should be reconsidered and withdrawn.

The Examiner asserts, in effect, that the antibody taught by Yu et al. will inherently cross-react with the same polypeptides (i.e., polypeptides comprising or consisting of SEQ ID NO:2) as the instantly claimed antibodies, thereby anticipating the instant claims. However, inherency may only be relied upon where the consequences of following the reference disclosure always necessarily results in the claimed invention. If there is not a reasonable certainty that the claimed subject matter will necessarily result, the rejection is not proper.

Specifically, in order for the antibody of Yu et al. to inherently anticipate the instant claims, the antibody of Yu et al. must necessarily selectively bind to the polypeptides recited in the instant claims (i.e., polypeptides comprising or consisting of SEQ ID NO:2). It is not sufficient that the antibody of Yu et al. may possibly or probably bind to the polypeptides recited in the instant claims.

However, this "possibly or probably" standard appears to be the standard that the Patent Office is relying on for the rejection of claims 3 and 27-39 under 35 USC §102(e). The Examiner has cited a reference that teaches an antibody that may possibly or probably selectively bind to polypeptides of SEQ ID NO:2 because the reference antibodies bind to a protein that has an

amino acid sequence that is partially identical SEQ ID NO:2, without demonstrating that the reference antibodies must necessarily selectively bind to polypeptides of SEQ ID NO:2.

It is Applicant's position that the antibody of Yu et al. does not necessarily selectively bind to polypeptides of SEQ ID NO:2 because significantly different epitopes must necessarily exist in the polypeptide of SEQ ID NO:2 compared with the NHP protein of Yu et al. because of the extensive differences that exist in their amino acid sequences. For example, the amino acid sequence of instant SEQ ID NO:2 differs from the NHP protein of Yu et al. by not only the five amino acids at the C-terminus of instant SEQ ID NO:2 that are not included in the sequence of Yu et al., but also the additional 1702 amino acids that are present in the NHP protein of Yu et al. (which is 1958 amino acids in length) that are not present in instant SEQ ID NO:2 (which is 257 amino acids in length).

Thus, any epitopes in instant SEQ ID NO:2 that span any of the extra five amino acids amino acids at the C-terminus of instant SEQ ID NO:2 that are not included in the sequence of Yu et al. would not be present in the NHP protein of Yu et al. Similarly, any epitopes that span any portion of the additional 1702 amino acids that are present in the NHP protein of Yu et al. compared with instant SEQ ID NO:2 would not be present in instant SEQ ID NO:2. Because of the different epitopes present in each of instant SEQ ID NO:2 and the NHP protein of Yu et al., antibodies raised using one of these proteins will not necessarily cross-react with the other protein. Accordingly, not all antibodies raised using instant SEQ ID NO:2 would cross-react with the NHP protein of Yu et al., and not all antibodies raised using the NHP protein of Yu et al. would cross-react with instant SEQ ID NO:2.

Furthermore, because the NHP protein of Yu et al. has 1702 additional amino acids compared to instant SEQ ID NO:2, it is quite likely that any antibodies to the NHP protein disclosed by Yu et al. bind to epitopes spanning at least a portion of this 1702 amino acid region of the NHP protein. These epitopes are not present in instant SEQ ID NO:2 and thus any such antibodies disclosed in Yu et al. would not bind to instant SEQ ID NO:2. Therefore, these antibodies in Yu et al. would not be encompassed by the instant claims. Because there is a reasonable degree of likelihood that the antibodies disclosed by Yu et al. do not anticipate the instant claims, the rejection under 35 USC §102 is improper.

Therefore, due to the significant differences in the protein structures of the NHP protein of Yu et al. and instant SEQ ID NO:2, the antibody taught by Yu et al. does not necessarily cross-

react and selectively bind to the same proteins (i.e., proteins comprising or consisting of SEQ ID NO:2) as the antibodies of claims 3 and 27-39.

Accordingly, Applicants respectfully request that the rejection of claims 3 and 27-39 under 35 USC §102(e) be reconsidered and withdrawn.

Conclusions

Claims 3 and 27-39 remain pending and under consideration. Claims 12 and 24-26 were previously withdrawn.

In view of the above amendments and remarks, Applicants respectfully submit that the application and claims are in condition for allowance, and request that the Examiner reconsider and withdraw the rejections. If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is invited to call the undersigned agent at (240) 453-3812 should the Examiner believe a telephone interview would advance prosecution of the application.

Respectfully submitted,
CELERA GENOMICS

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By: _____
Justin D. Karjala, Reg No. 43,704

Celera Genomics Corporation
45 West Gude Drive
Rockville, MD 20850
Tel: 240-453-3812
Fax: 240-453-3084